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June 3, 2002

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 2216

Attn: Chemical Right-to-Know Program

Re: EPA comments on the Test Plan and Robust Data Summary for 4,4'-Oxydianiline (CAS#101-80-4)

Dear Administrator Whitman,

E. I. du Pont de Nemours & Company, Inc. received EPA's comments on the test plan and robust data summary for 4,4'-oxydianiline (CAS# 101-80-4) and is please to respond. We have considered the recommended revisions to the physiochemical and environmental fate studies and ecotoxicity studies, as well as, EPA's specific comments on the robust data summaries. We have revised our submittal as needed on the attached summary sheet. Also included with this submittal is a revised robust data summary.

Please feel free to contact me with any questions or concerns you may have with regards to this submission at Edwin.L.Mongan-1@usa.dupont.com or by phone at 302-773-0910.

Sincerely,

Edwin L. Mongan, III
Manager, Environmental Stewardship
DuPont Safety, Health & Environment

Cc: Charles Auer – U.S. EPA
Office of Pollution Prevention & Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

General Comment

EPA comment: The submitter needs to add a "Remarks" section to the robust summaries in which the data from the additional references listed can be presented and discussed in the context of the main study.

Response: Existing published and unpublished data were collected and scientifically evaluated to determine the best possible study or studies to be summarized for each required endpoint. The EPA additionally recommends "whether used or not, it is prudent to make publicly available all the studies reviewed, possibly in the form of a bibliography." In the spirit of this voluntary program, studies not summarized in the document were listed at the end of each appropriate section as additional references, with a statement to reflect the reason why these studies were not summarized. If the EPA has questions regarding a specific study listed as an additional reference, the requested information will be provided. However, since a majority of the additional studies listed are published and available publicly, DuPont does not believe it prudent at this time to provide the data for all the additional studies.

Physiochemical and Environmental Fate Data

EPA comment: The submitter needs to provide measured data for solubility in water.

Response: Water solubility will be measured following ASTM E-1148-02. The test plan has been revised to reflect this recommendation.

EPA comment: The planned biodegradation test should follow OECD Guideline 301 for ready biodegradability.

Response: Test plan was revised to include that the proposed biodegradation test will follow OECD Guideline 301.

EPA comment: The sponsor's treatment of transport (fugacity) is adequate, except that the sponsor needs to provide half-life data inputs to the model.

Response: Requested data were added to the robust summary.

Ecological Effects

EPA comment: The fish study duration of 24 hours is shorter than the required 96 hours for assessing the acute toxicity of 4,4'-oxydianiline. An ECOSAR prediction alone cannot be used to support the existing 24-hour fish toxicity study, nor used in the absence of test data for the algae endpoint, to determine the toxicity of this chemical. The submitter needs to provide adequate measured data on related chemicals for these endpoints to support the predicted data.

Response: No measured data on related chemicals were found. Therefore, acute toxicity tests in fish and algae will be performed following OECD Guidelines 203 and 201, respectively. The test plan has been revised to reflect this recommendation.

Health Effects

EPA comment: In the ALD acute oral study, the submitter needs to report death rates at each dose. In the summary of the other oral LD_{50} study, the submitter needs to report the strain of rat and the standard deviation for the rat LD_{50}. In addition, EPA recommends that an LD_{50} value for mice, which was reported in the NCI citation for the repeat dose toxicity robust summaries be included in the remarks section to strengthen this endpoint.

Response: Where available, data was added to address the missing/requested information.

EPA comment: The submitter needs to provide data for non-neoplastic lesions and data on histopathology in the robust summaries of both 2-year feeding studies.

Response: Requested data were added to the robust summary.

EPA comment: The submitter needs to add the following information where available:

Reverse mutation in Salmonella typhimurium. The number of mutants for each concentration and strain of *Salmonella* tested.

Chromosomal aberration in Chinese hamster ovary cells. The number and type of chromosomal aberrations per metaphase and per chromosome, if such data are available.

In vivo micronucleus test in mice. The effects (mitotic index, micronucleus frequency, or clinical signs) observed at each dose level and time period examined.

Response: Where available, data was added to address the missing information.

EPA comment: The robust summary needs to clearly state levels (NOAEL/LOAEL) for both maternal and offspring toxicity.

Response: Requested data were added to the robust summary.